IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Takaki Koga et al.	Art Unit	: 1644
Patent No.	: 7,517,965	Examiner	: Michael Edward Szperka
Issue Date	: April 14, 2009	Conf. No.	: 9242
Serial No.	: 10/522,086		
Filed	: October 5, 2005		
Title	: NON-NEUTRALIZING ANTI-APC ANTIBODIES		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 268 to 716 days, is respectfully requested.

REMARKS

(1) Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F. Supp. 2d 138; 88 USPQ 2d 1538), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: June 11, 2009

determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the "overlap" issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Patentee's understanding that for purposes of calculating "B Delay," the Office measured application pendency as beginning on October 5, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the relevant statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application i.e., January 22, 2005, not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371.

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.
> 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins

if the Office fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f)."[1]

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including… 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

> (f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

[1] Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that "[i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f)."

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39
Copy, Translation, and Fee, to Elected Offices

(1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences

under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

> Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01. (emphasis added)

In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.[2]

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

"A Delay"

A first PTO action was due on or before December 5, 2006 (the date that is fourteen months after October 5, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on November 11, 2007, thereby according a PTO Delay of 360 days. Patentee does not dispute the PTO's calculation for this "A Delay." See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 360 days.

---

[2] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 37 C.F.R. § 1.702(a)(1).

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP2003/009087, filed July 17, 2003, which claims the benefit of priority of Japan application number 2002-212582, filed July 22, 2002.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application.[3] As a result, the date that the national stage commenced was January 22, 2005 (i.e., 30 months from the priority date of July 22, 2002).

The period beginning on January 23, 2008 (the day after the date that is three years after January 22, 2005, the date that the national stage commenced) and ending April 14, 2009 (the date the patent was issued) is 448 days in length.

"B Delay" may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In the present application, no Request for Continued Examination was filed.

In addition, "B Delay" may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a Notice of Allowance. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4). In the present application, no Notice of Appeal was filed.

In view of the periods of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 448 days. The PTO calculated 0 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 448 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

December 6, 2006, to November 11, 2007.

[3] A complete request for early processing under 35 U.S.C. § 371(f) was not filed with the present application.

As detailed above, "B Delay" accumulated during the following period:

January 23, 2008, to April 14, 2009.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day). Thus, Applicants submit that the total PTO Delay should be calculated as 808 days (i.e., the sum of 360 days of "A Delay" and 448 days of "B Delay").

In the event that the Office declines to follow the rules on overlapping A and B delays set forth in the *Wyeth* decision, the date the Office would use to begin calculating the application's pendency would be the date of commencement of the national stage (i.e., 30 months from the priority date of the international application). As the national stage commenced in the present case on January 22, 2005, the Office would consider any time between January 22, 2005, and January 22, 2008 to overlap with any "A Delay" accruing during that period. As the 360 days of "A Delay" accrued during that time (from December 6, 2006, to November 11, 2007), the Office should calculate a period of 88 days (448 days of "B Delay" minus 360 days of "A Delay") of "B Delay" that does not overlap with "A Delay." In other words, even in the absence of the rules set forth in the *Wyeth* decision, the present patent should still be entitled to 88 days of "B Delay." In that case, the total PTO Delay should be calculated as 448 days (i.e., the sum of 360 days of "A Delay" and 88 days of "B Delay").

Applicant Delay

A reply to an Office Action was due on or before June 10, 2008 (the date that is three months after March 10, 2008, the date on which the Office Action was mailed). Patentee filed a response to the Office Action on September 10, 2008, thereby according an Applicant Delay of 92 days. Patentee does not dispute the PTO's calculation for this Applicant Delay from June 11, 2008 (the day after the date that is three months after the date on which the Office Action was mailed) to September 10, 2008. See 37 C.F.R. § 1.704(b).

In view of the period of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 92 days.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes the PTA calculation of 268 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

1) Total PTO Delay should be calculated as 808 days (i.e., the sum of 360 days of "A Delay" and 448 days of "B Delay");

2) Total Applicant Delay should be calculated as 92 days; and

3) Total PTA should be calculated as 716 days.

The fee of $200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 14875-0138US1.

Respectfully submitted,

Date: June 11, 2009

/Tony Zhang/
Tony Zhang, Ph.D.
Reg. No. L0256

Fish & Richardson P.C.
PTO Customer No. 26161
Telephone: (212) 765-5070
Facsimile: (877) 769-7945